



UNITED STATES DEPARTMENT OF COMMERCE
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DK

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/334, 537	06/16/99	ACHARI	R 719-163

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EXAMINER
OKE, V

ART UNIT
1617

DATE MAILED: 11/26/99

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/334,537	ACHARI ET AL.
Examiner	Art Unit	
Victor Oke	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) All b) Some * c) None of the CERTIFIED copies of the priority documents have been:
 - 1: received.
 - 2: received in Application No. (Series Code / Serial Number) _____.
 - 3: received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 14) <input type="checkbox"/> Notice of References Cited (PTO-892) | 17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 15) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 16) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 19) <input type="checkbox"/> Other: _____ |

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Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1 through 15 drawn to Intranasal morphine formulation, classified in class 514, subclass 282 and 424, subclass 434.
- II. Claim 16 through 29, drawn to the method of using the formulation, classified in class 424-subclass 434 and class 514, subclass 282.

Inventions of group I and group II drawn to an Intranasally administered morphine formulation and method of use are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method as disclosed for eliciting an analgesic or anesthetic response can be practiced with another materially different product, such as a composition containing naloxone, or nalbuphine.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A further election of a species is also required for groups I and II. This application contains claims directed to the following patentably distinct species of the claimed

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invention: A. claims 7and 21, directed to various dosage forms i.e. suspensions, solutions, powders, gels, ointments and creams;

B. claim 11, directed to various buffers i.e. acetate, citrate, prolamine carbonate, phosphate and combinations thereof;

C. claim 12, directed to various thickening agent i.e. methyl cellulose, carbomer, xanthan, gum, carboxymethyl cellulose, hydroxypropyl cellulose, polyvinyl alcohol, alginates, acacia, chitosan, and combinations thereof;

D. claim 13, directed to humectant i.e. sorbitol, glycerol, mineral oil, vegetable oil, and combinations thereof;

E. claims 14 and 15, directed to various absorption enhancers i.e. sodium lauryl sulphate, oleic acid, lecithin, dehydrated alcohol, tween, span, polyoxyl 40 stearate, polyoxy ethelene 50 stearate, edetate disodium, propylene glycol, glycerol monooleate, fusieates, bile salt, octoxynol, and combinations thereof;

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-10, 15-24, and 29 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Because the above restriction/election requirement is complex, a telephone call to the attorney to request an oral election was not made. (see MPEP 812.01)

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor Oke whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday to Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams (Ph.D.), can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Victor Oke

11/19/99



MINNA MOEZIE
PRIMARY EXAMINER